

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
ALEXANDRIA DIVISION

PATSY WINSLOW

CIVIL ACTION NO. 10-116

VERSUS

U.S. DISTRICT JUDGE DEE D. DRELL

W. L. GORE & ASSOC, INC.,
et al

U.S. MAGISTRATE JUDGE JAMES D. KIRK

REPORT AND RECOMMENDATION

Before the court is a Motion to Dismiss, doc. #21, referred to me by the district judge for report and recommendation.

This is a products liability suit which alleges that six years ago a mesh medical device was implanted in hernia surgery. The suit alleges that, because of continued problems, exploratory surgery was performed which revealed that the mesh device, manufactured by the defendant, had failed and that it was found in a deteriorated condition. The suit alleges that the device was defective and resulted in damages and injuries including infection and the necessity for the second surgery.

Defendant seeks to dismiss based on the language of Bell Atlantic v. Twombly, 550 U. S. 544 (2007), and Ashcroft v. Iqbal, 129 S. Ct. 1937 (2009). Specifically, defendants assert that the plaintiff's complaint is deficient because it does not contain the requisite factual detail as required by the two cases. Plaintiff argues that the complaint contains the facts she has but nevertheless has filed a separate motion to amend her complaint to more specifically plead defendant's fault.

Defendants also argue that some of plaintiff's claims are not cognizable under the Louisiana Products Liability Act, which provides the exclusive method of making claims against manufacturers of defective products, and must be dismissed.

Law and Analysis

12(b)6 motion to dismiss

In considering a motion to dismiss, the court must assume the truth of factual allegations of the complaint and liberally construe them in favor of the plaintiff. A motion to dismiss an action for failure to state a claim admits the facts alleged in the complaint, but challenges plaintiff's right to relief based upon those facts. Crowe v. Henry, 43 F.3d 198, 203 (5th Cir. 1995). While a complaint sought to be dismissed under FRCP 12(b)(6) does not need detailed factual allegations, a plaintiff must provide more than conclusions or speculation. A formulaic recitation of the elements of a cause of action will not suffice. In other words, plaintiff must make a showing rather than a blanket assertion of entitlement to relief. Bell Atlantic Corp. v. Twombly, 127 S.Ct.1955 (2007). This court has long held that a Rule 12(b)(6) motion may be granted as to portions of a complaint. Drewett v. Aetna Cas. & Sur. Co., 405 F.Supp. 877 (W.D. La. 1975). In accord, *see* Decker v. Massey-Ferguson, Ltd., 681 F.2d 111 (2nd Cir. 1982); Elliott v. State Farm Mut. Auto Ins. Co., 786 F.Supp. 487 (E.D.Pa. 1992). A well pleaded complaint may proceed even if it appears that actual proof of the facts set forth is improbable. Once a claim has been stated adequately, it may be supported by proof of any set of facts consistent with the allegations in the complaint. Bell, *supra*.

Motions to dismiss are viewed with disfavor and are rarely granted. Lormand v. US Unwired, Inc., 565 Fed.3d 228 (5th Cir. 2009).

Louisiana law of products liability

_____ In Louisiana, the LPLA “establishes the exclusive theories of liability for manufacturers for damage caused by their products”. L.S.A.-R.S. 9:2800.52; Caboni v. General Motors Corp., 398 F.3d 357 (5th Cir. 2005). A claimant may not recover on the basis of any theory not set forth in the

LPLA. Jefferson v. Lead Indus. Assoc., Inc. 106 F.3d 1245, 1250-51 (5th Cir. 1997).

_____ In order to recover, a plaintiff must prove (1) that the damages were proximately caused by the characteristic of the product that renders it unreasonably dangerous, and (2) the damages arose from a “reasonably anticipated use of the product”. Kampen v. American Isuzu Motors, Inc., 157 F.3d 306 (5th Cir. 1998).

The LPLA defines reasonably anticipated use as “a use or handling of the product that the product’s manufacturer should reasonably expect of an ordinary person in the same or similar circumstances. La. R.S. 9:2800.53(7). Use of the product contrary to warnings is, as a matter of law, not a reasonably anticipated use. Kampen, supra. In determining whether a particular use is reasonably anticipated, several factors may be considered, including whether the injured party used the product in a manner that was obviously dangerous, what the user was instructed to do and warned not to do with respect to the use of the product, whether the use of the product was expressly warned against in the product’s labeling (or operations manual) and the language of that warning, and the sophistication and experience of the user. Broussard v. Procter and Gamble Co. 2006 WL 3392759 (W.D. La. 2006).

A plaintiff must also prove that the product is “unreasonably dangerous” under one of the four theories of liability set forth in the act: (1) a defect in construction or composition (manufacturing), (2) defect in design, (3) inadequacy of warning, or (4) failure to conform to an express warranty. See Stahl v. Novartis Pharmaceuticals Corp., 283 F.3d 254 (5th Cir. 2002). To maintain an action under any of the theories, a plaintiff must establish that the defendant is the manufacturer of the product. Stahl v. Novartis Pharmaceuticals Corp., 283 F.3d 254, 260-261 (5th Cir. 2002).

In this case, plaintiff claims that the mesh device was defective in manufacture and design, and alleges failure to warn, asserts a claim of warranty and also asserts claims of fraud/misrepresentation, and fraud/misrepresentation to the FDA (Food & Drug Administration).

Because the claims of fraud and misrepresentation and fraud/misrepresentation to the FDA and breach of implied warranty are not recognized under the LPLA, they should be dismissed.

Defendant points out that under Twombly and Iqbal a plaintiff must provide more than labels, conclusions and formulaic recitations of the elements of a cause of action to survive a motion to dismiss. It must contain sufficient factual matter that is plausible on its face. Here, defendants argue, plaintiffs have not alleged a single fact that would permit the court to draw the reasonable inference that Gore is liable. It also argues that plaintiff fails to identify the alleged defect and fails to identify any safer design. Defendants also suggest that plaintiff has failed to properly plead the elements of a warranty claim.

Plaintiffs have adequately set forth facts regarding a products claim. She has specifically identified the “nature of the alleged defect” as being deterioration of the mesh device. Regarding a design defect, plaintiff has at least implicitly pled alternative design. Clearly, an alternative design would be one which does not deteriorate. While defendants are correct in their quoting of Twombly and Iqbal, it must be remembered that neither was a products liability suit. While the pronouncements in the cases are nonetheless applicable, this is a products liability case where almost all of the evidence is in the possession of defendant or other entities. Proof will necessarily be technical in nature and it is likely impossible for plaintiff to state more specific allegations regarding defects in manufacture and design without first having the benefit of discovery and of expert

analysis, neither of which is required in order to file suit.¹

Further, in this case, it may be that the nature of the incident is itself sufficient proof of a defect. The principle of *res ipsa loquitur* may be utilized to prove a claim under the LPLA. Spott v. Otis Elevator Co., 601 So.2d 1355 (La. 1992); State Farm Mut. Auto. Ins. Co. v. Wrap-On Co., Inc., 626 So.2d 874 (La.App. 3 Cir. 1993), *writ den.*, 630 So.2d 800 (La. 1994); Baptiste v. General Motors Corp., 802 So.2d 686 (La.App. 4 Cir. 2001); Marks v. Dupre Transport, Inc., 2002 WL 31319940 (E.D.La. 2002). The principle of *res ipsa loquitur* is a principle of circumstantial evidence which is evidence of a fact or facts from which facts sought to be proven may be inferred. State Farm Mut. Auto. Ins. Co. v. Wrap-On Co., Inc., *supra*. A manufacturing defect may be established by circumstantial evidence under the evidentiary doctrine of *res ipsa loquitur* under circumstances in which “the only reasonable and fair conclusion is that the accident resulted from a breach of duty or omission on the part of the defendant.” Jurks v. Ford Motor Co., 752 So.2d 260, 265 (La.App. 2 Cir. 2000). The doctrine is used where the facts indicate that the defendant’s negligence, more probably than not, caused the damage. Spott v. Otis Elevator Co., *supra*, at 1362.²

Regarding the express warranty allegation (if indeed one is being made), plaintiff should be allowed to amend her complaint to more specifically state whatever information she may have

¹ Defendant’s argument that plaintiff has not adequately alleged the nature of the defect is somewhat disingenuous. Is Gore, through counsel, really suggesting that it is normal for its mesh device to only last for six years, thereby requiring all patients who use its device to have repeat hernia repair surgeries every six years?

² The doctrine is sparingly applied and generally requires three elements: (1) the circumstances surrounding the accident are so unusual that, in the absence of other pertinent evidence, there is an inference of negligence by the defendant; (2) the defendant had exclusive control of the thing causing the damage; and (3) the only reasonable and fair conclusion is that the accident was due to the defendant’s breach of a duty.

regarding her warranty claim. However, again, warranty information on a medical device is likely to be in the possession of the defendant, not the patient. Defendant also asserts that plaintiff failed to recite the elements of a warranty claim; however, as defendant points out elsewhere in its brief, recitation of the elements of the cause of action is inadequate.

Dismissal of a claim is not appropriate when the pleadings demonstrate plausible allegations to support a claim. Iqbal, supra. Here, plaintiff has presented plausible factual allegations for her claim. As plaintiff's counsel has well stated it:

Plaintiff has sufficiently pled that Gore manufactured the mesh device used in the hernia repair of Patsy Winslow in 2003, that the mesh device caused injuries as alleged (deterioration of the mesh resulting in failed surgery, infection, weakness, adhesions, etc.), the mesh device was unreasonably dangerous (manufacturing a device such that it would deteriorate and cause infection) and that the damage arose from a reasonably anticipated use of the product (surgery for repair of a hernia). Plaintiff has sufficiently pled causes of action to support a plausible factual claim for relief. This is sufficient at the pleadings stage.

Defendant is sufficiently put on notice of plaintiff's claims and the basis thereof.

I agree. The Supreme Court made clear that the standard set forth in Twombly "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary claims or elements. Twombly, at 566. It is not unreasonable to assume that discovery will uncover evidence which tends to prove a defect in the manufacture and design which in turn led to the deterioration of the mesh device.

Considering the nature of the case and recognizing that motions to dismiss are viewed with disfavor and are rarely granted, I find that the motion to dismiss should be denied.

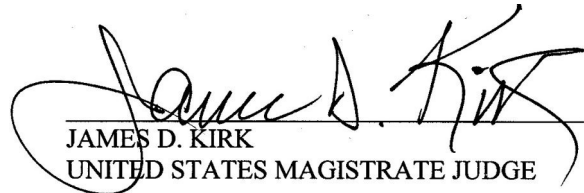
Therefore, IT IS RECOMMENDED that the motion to dismiss, doc. #21, be DENIED, and that plaintiff be allowed, if she wishes, to amend her complaint. IT IS FURTHER RECOMMENDED that plaintiff's claims regarding implied warranty, fraud and misrepresentation and fraud and misrepresentation to the FDA, be DISMISSED.

OBJECTIONS

Under the provisions of 28 U.S.C. § 636(b)(1)(C) and Fed.R.Civ.P. 72(b), the parties have fourteen (14) calendar days from service of this Report and Recommendation to file specific, written objections with the clerk of court. No other briefs or responses (such as supplemental objections, reply briefs etc.) may be filed. A party may respond to another party's objections within fourteen (14) days after being served with a copy thereof. A courtesy copy of any objection or response or request for extension of time shall be furnished to the district judge at the time of filing. Timely objections will be considered by the district judge before he makes his final ruling. **FAILURE**

TO FILE WRITTEN OBJECTIONS TO THE PROPOSED FINDINGS, CONCLUSIONS, AND RECOMMENDATIONS CONTAINED IN THIS REPORT WITHIN FOURTEEN (14) CALENDAR DAYS FROM THE DATE OF ITS SERVICE SHALL BAR AN AGGRIEVED PARTY, EXCEPT UPON GROUNDS OF PLAIN ERROR, FROM ATTACKING ON APPEAL THE UN-OBJECTED-TO PROPOSED FACTUAL FINDINGS AND LEGAL CONCLUSIONS ACCEPTED BY THE DISTRICT JUDGE.

THUS DONE AND SIGNED in chambers, in Alexandria, Louisiana, on this 19th day of January, 2011.


JAMES D. KIRK
UNITED STATES MAGISTRATE JUDGE